



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0360]

MDEpiNet 2012 Annual Meeting: The Medical Device Epidemiology Network as a Partnership for Building Global Medical Device Epidemiology and Surveillance Capabilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the following public workshop entitled "MDEpiNet 2012 Annual Meeting: The Medical Device Epidemiology Network as a Partnership for Building Global Medical Device Epidemiology and Surveillance Capabilities." The topic to be discussed is setting strategic priorities and implementing an action plan for sustainable partnership toward improving regulatory science and the public health.

**DATES:** The public workshop will be held on September 11, 2012, from 8 a.m. to 5 p.m.

**ADDRESSES:** The public workshop will be held at the Greenbelt Marriott Hotel, 6400 Ivy Lane, Greenbelt, MD 20770, 301-441-3700.

**FOR FURTHER INFORMATION CONTACT:** Danica Marinac-Dabic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4110, Silver Spring, MD 20993, 301-796-6689, email: [Danica.Marinac-Dabic@fda.hhs.gov](mailto:Danica.Marinac-Dabic@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

**Registration:** Registration is free and available on a first-come, first-served basis.

Persons interested in attending this public workshop must register online by 5 p.m., September 10, 2012. Early registration is recommended because facilities are limited and, therefore, FDA

may limit the number of participants from each organization. Onsite registration will not be available on the day of the workshop.

If you need special accommodations due to a disability, please contact Joyce Raines, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4319, Silver Spring, MD 20993, 301-796-5709, email: [joyce.raines@fda/hhs.gov](mailto:joyce.raines@fda/hhs.gov); no later than September 5, 2012.

To register for the public workshop, please visit FDA's Medical Devices News & Events-Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Danica Marinac-Dabic (see [Contact Person](#)) to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m., September 5, 2012. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after September 7, 2012.

Comments: FDA is holding this public workshop to provide updates and obtain stakeholders' input on the Medical Device Epidemiology Network (MDEpiNet) as a partnership for building global medical device epidemiology and surveillance capabilities. In order to permit

the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the workshop topics. The deadline for submitting comments related to this public workshop is October 9, 2012.

Regardless of attendance at the meeting, interested persons may submit either written comments regarding this document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or electronic comments to <http://www.regulations.gov>. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.)

## I. Background

MDEpiNet is a collaborative program through which the Center for Devices and Radiological Health and external partners share information and resources to enhance our understanding of how well medical devices work (<http://www.fda.gov/mdepinet>). By bridging evidentiary gaps, developing datasets, and innovating methodological approaches for conducting robust analytic studies, MDEpiNet aims to develop new ways to study medical devices that improve the understanding of safety and effectiveness performance throughout a device's life cycle.

Accomplishing MDEpiNet's mission will require leveraging of resources, skills, and expertise from a variety of partners, and we encourage participation from all stakeholders, including other Government Agencies, academia, health care industry organizations, and patient and consumer groups. The purpose of the public workshop is to facilitate discussion among these key stakeholders in the scientific community on issues related to medical device epidemiology methodology and infrastructure as it relates to evidence generation and synthesis across the Total Product Life Cycle. This public workshop is open to all interested parties. The target audience is professionals from other Government Agencies, academia, professional societies, health care industry organizations, patient and consumer groups, and other professionals in the scientific community interested in advancing the infrastructure and methodology for epidemiologic understanding of medical devices and procedures.

## II. Topics for Discussion at the Public Workshop

We intend to discuss a large number of issues at the public workshop, including but not limited to the following: (1) Status and updates from MDEpiNet Methodology and Infrastructure Centers; (2) proposed partnership structure and governance; (3) MDEpiNet as a framework for

medical device postmarket surveillance and its relation to the Sentinel provision in the FDA Safety and Innovation Act (calling for the expansion of the postmarket risk identification and analysis system to include devices); and (4) action plan and prioritization of MDEpiNet partnership efforts for the upcoming year.

Dated: August 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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